

The Proposed Drug Quality and Security Act (H.R. 3204)

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Summary

The proposed Drug Quality and Security Act, H.R. 3204, is the current focus of congressional efforts to protect the public from unsafe, ineffective, or otherwise subquality compounded drugs and from the risks of counterfeit and subquality drugs entering the supply chain between the manufacturer and the dispenser. Majority and minority leadership of the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor, and Pensions announced an agreement on September 25, 2013, following years of bicameral and bipartisan efforts. On September 27, 2013, Representative Fred Upton, the chair of the House committee, introduced the text, which would amend the Federal Food, Drug, and Cosmetic Act (FFDCA), as H.R. 3204. The House passed it by voice vote on September 28, 2013, sending it to the Senate on September 30, 2013. The bill now awaits Senate action.

Title I, the Compounding Quality Act, would create the term *outsourcing facility* to apply to an entity that compounds sterile drugs in circumstances that go beyond activities that the FFDCA allows pharmacies to do under state regulation. As such, the proposed category could be conceptualized somewhere between a state-regulated pharmacy and a federally regulated drug manufacturer. The bill would direct the Secretary of Health and Human Services (HHS) to consult with the National Association of Boards of Pharmacy regarding submissions from states that concern a compounding pharmacy that may be acting outside what the FFDCA allows. The bill would also maintain the FFDCA section that addresses what is referred to as traditional compounding—wherein a pharmacist or physician compounds a drug to fill a prescription written for an individual patient. It would remove the provision, which has been challenged in court, that forbids a compounder from advertising or promoting a compounded drug.

An entity that compounds sterile drugs and that may not obtain prescriptions for identified individual patients would be able to voluntarily register as an outsourcing facility. If it also complies with a set of listed requirements, an outsourcing facility would be exempt from certain FFDCA requirements on drug manufacturers: adequate directions for use labeling, sale only after FDA approval of a new drug application, and compliance with supply chain activities (that would be added by Title II of H.R. 3204). An outsourcing facility would have to label the product to include the statement “This is a compounded drug,” list active and inactive ingredients, report annually to the HHS Secretary on drugs compounded, be subject to inspection, submit adverse event reports, and pay annual fees (that would be established by this bill) to cover the cost of overseeing outsourcing facilities.

Title II, the Drug Supply Chain Security Act, would add FFDCA requirements to be implemented over the next few years. These include that manufacturers and repackagers put a product identifier, including a standardized numerical identifier, on each package or homogenous case. With certain exceptions, exchange of transaction information, histories, and statements would be required when a manufacturer, wholesale distributor, dispenser, or repackager transfers or accepts a drug. Also required would be a system of verification and notification when the Secretary or a trading partner within the supply chain suspects that a product may be illegitimate. The bill would require national standards for the licensing of wholesale distributors and third-party logistics providers. Requirements for the Secretary would include guidance documents, regulations, public meetings, and pilot projects.

The act also would include a timetable and tasks involving the development of an interoperable, electronic, package-level tracking system to begin 10 years after enactment.

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Introduction

Over several congresses, policymakers have been interested in drug compounding and pharmaceutical supply chain security¹ and have worked to craft legislation to enhance the Food and Drug Administration (FDA) ability to protect the public.² On September 25, 2013, the leadership of the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce announced an agreement on a bill to cover both topics.³ The House passed H.R. 3204, the Drug Quality and Security Act, which now awaits Senate action. Title I is the proposed Compounding Quality Act. Title II is the proposed Drug Supply Chain Security Act.

This report provides an overview of the provisions in H.R. 3204, as passed by the House. This report does not discuss policy implications of the potential passage and implementation of provisions in the bill.

Compounding Quality Act

Under current law, the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 USC 301 et seq.), the federal government regulates drug manufacturing and sales within the United States. However, the FFDCA provides specific conditions in which a drug may be compounded—primarily that the compounding is done by a pharmacist or physician based on a prescription for an individual patient—for which several FFDCA requirements of manufacturers do not apply. Such compounding is regulated by the states within their authority over the practice of pharmacy. There are, however, entities that perform activities that do not fit within this limited sphere of compounding. Federal regulators, the pharmacy and manufacturing industries, state authorities, and various courts have had differing opinions on who has jurisdiction—FDA or the states—over those activities. Title I of H.R. 3204, the proposed Compounding Quality Act, attempts to address some of these issues. The act would, among other things:

¹ Several CRS reports have described the issues underlying legislative efforts; for example CRS Report R43106, *Pharmaceutical Supply Chain Security*, by Susan Thaul; CRS Report R43038, *Federal Authority to Regulate the Compounding of Human Drugs*, by Andrew Nolan; and CRS Report R40503, *FDA's Authority to Regulate Drug Compounding: A Legal Analysis*, by Jennifer A. Staman; archived CRS Report R43082, *Compounded Drugs*; and archived CRS Report R42837, *Selected Resources on Federal Oversight of Compounding Pharmacies*.

² Members have introduced several bills that would have addressed issues in compounding, supply chain security, or some combination of the two. For example, in the 113th Congress: H.R. 1919, Safeguarding America's Pharmaceuticals Act of 2013, S. 957, Drug Supply Chain Security Act, and S. 959, Pharmaceutical Quality, Security, and Accountability Act; several publicly available staff discussion drafts; and H.R. 2186, VALID Compounding Act. Bills introduced in previous Congresses include H.R. 6584, Verifying Authority and Legality in Drug Compounding Act of 2012 [112th]; H.R. 6638, S.A.F.E Compounded Drugs Act of 2012 [112th]; publicly distributed discussion draft of the Safe Compounding Drug Act of 2007 [110th]; H.R. 1060, Pharmacy Compounding Act [105th]; H.R. 1411, Drug and Biological Products Modernization Act of 1997 [105th]; H.R. 1411, Prescription Drug User Fee Reauthorization and Drug Regulatory Modernization Act [105th]; H.R. 598, Pharmacy Compounding Preservation Act of 1994 [104th]; and H.R. 3199, Drug and Biological Products Reform Act of 1996 [104th].

³ Senate Committee on Health, Education, Labor, and Pensions and House Committee on Energy and Commerce, "Senate, House Health Policy Leaders Announce Bipartisan, Bicameral Legislation to Address High-Risk Drug Compounding Practices and Secure the Pharmaceutical Supply Chain," September 25, 2013, Senator Harkin press release, (<http://www.help.senate.gov/newsroom/press/release/?id=549b94cd-bca0-470d-aa39-3cfe1cea055f&groups=Chair>); Senator Alexander press release (<http://www.help.senate.gov/newsroom/press/release/?id=72249936-5a6e-4121-a3a7-78cf9d6588e9&groups=Ranking>); Representative Upton press release (<http://energycommerce.house.gov/press-release/senate-house-health-policy-leaders-announce-bipartisan-bicameral-legislation-address>); Representative Waxman press release (<http://democrats.energycommerce.house.gov/index.php?q=news/senate-house-health-policy-leaders-announce-bipartisan-bicameral-legislation-to-address-high-ri>).

- maintain FDA authority to regulate drug compounding that goes beyond the scope of state-regulated practice of pharmacy;
- establish a new category of compounding entity, termed “outsourcing facility,” which would apply to entities that compound sterile drugs, volunteer to register with FDA, and follow practice and reporting requirements;
- require that the label of a drug from an outsourcing facility state “This is a compounded drug”;
- dictate user fees to fund outsourcing facility registration and reporting; advisory committee activities; annual reports; the issuing of regulations; and a study by the Government Accountability Office (GAO); and
- direct enhanced communication among state boards of pharmacy and between those boards and the FDA.

(4)(A) The term ‘**outsourcing facility**’ means a facility at one geographic location or address that—

(i) is engaged in the compounding of sterile drugs;

(ii) has elected to register as an outsourcing facility; and

(iii) complies with all of the requirements of this section.

(B) An outsourcing facility is not required to be a licensed pharmacy.

(C) An outsourcing facility may or may not obtain prescriptions for identified individual patients.

—definition from H.R. 3204, Sec. 102

To do so, Title I would amend FFDCA Section 503A [21 USC 353a] on pharmacy compounding and add a proposed Section 503B⁴ on outsourcing facilities as well as proposed Sections 744J and 744K to give FDA the authority to assess and use outsourcing facility fees.

FFDCA Section 503A, Pharmacy Compounding

Several provisions in Title I reflect challenges FDA has encountered in implementing FFDCA Section 503A [21 USC 353a], Pharmacy Compounding, in current law.⁵ H.R. 3204 would amend that section by removing the provision in current law that restricts a compounder from advertising or promoting a compounded drug. Relatedly, it would also remove the modifier “unsolicited” from the phrase “valid prescription” in referring to what the pharmacy must receive before compounding a drug. H.R. 3204 includes a severability provision indicating that, in the event a provision of the act is declared unconstitutional, the remaining provisions would be unaffected.

The remaining provisions in FFDCA Section 503A lay out the circumstances in which a state-regulated pharmacy may compound a drug. Although current law does not use the term, Members of Congress, FDA officials, and others often refer to this as *traditional compounding*. It involves compounding by a licensed pharmacist or physician in response to a prescription for an individual patient. The section describes what ingredients may be used, what kinds of drugs may not be compounded, required consultation between the HHS Secretary and the National Association of Boards of Pharmacy, and required implementing regulations.

⁴ The existing Section 503B would be re-designated 503C.

⁵ Court reactions to the advertising and promotion provision (Sec. 503A(c)) have muddled the standing of the entire section; see CRS Report R43038, *Federal Authority to Regulate the Compounding of Human Drugs*, by Andrew Nolan.

Outsourcing Facilities

For facilities that compound drugs in ways that go beyond the circumstances described by FFDCA Section 503A [21 USC 353a], a proposed Section 503B would allow an entity to voluntarily register as an *outsourcing facility*. For an outsourcing facility that follows the requirements described in the proposed Section 503B, certain existing requirements that apply to drug manufacturers would be waived. These are:

- a drug's labeling must provide adequate directions for use or be deemed misbranded (Sec. 502(f)(1)) [21 USC 352];
- a manufacturer may sell a drug in the United States only after FDA has approved its new drug application based on evidence of safety and effectiveness and other requirements regarding manufacturing processes, labeling, and reporting (Sec. 505 [21 USC 355]); and
- supply chain entities (manufacturers, wholesale distributors, dispensers, and repackagers) must comply with activities that would be required by Title II of this Act (proposed Sec. 582).

The proposed Section 503B would include requirements that focus on the drug, the outsourcing facility, and the Secretary. A drug that is compounded in a registered outsourcing facility would have to meet the following conditions:

- may not be made from bulk drug substances unless they comply with limitations specified in this bill on use of bulk drug substances and other ingredients;
- may not be a drug that has been withdrawn or removed from the market because it was found to be unsafe or not effective;
- may not be “essentially a copy of one or more approved drugs”;
- may not be on the Secretary's list of “drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients” unless compounding is done “in accordance with all applicable conditions identified on the list ... as conditions that are necessary to prevent” such difficulties;
- if it is subject to a risk evaluation and mitigation strategy (REMS),⁶ the outsourcing facility must demonstrate a plan to use “controls comparable to the controls applicable under the relevant” REMS;
- may be sold or transferred only by the outsourcing facility that compounded it;
- must be compounded in an outsourcing facility that has paid fees (as would be established in this Act);
- must have a label that includes the statement “This is a compounded drug.” (or comparable statement); must also contain specified identifying information of the outsourcing facility and the drug to include lot or batch number, established drug

⁶ In 2007, Congress added a structure and enforcement authority to FDA's risk management toolbox. FDA may require a risk evaluation and mitigation strategy (REMS), linked to a drug's approval, when it determines that it is necessary to ensure that the benefits of a drug outweigh its risks. A REMS may include instructions to patients and clinicians, restrictions on distribution or use, or elements to assure safe use (such as required training or certification of prescribers, pharmacies, or healthcare settings; laboratory tests; or patient monitoring or registries). See FFDCA Sec. 505-1 [21 USC 355-1]. Risk evaluation and mitigation strategies; and CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by Susan Thaul.

- name, dosage form and strength, quantity or value, date compounded, expiration date, storage and handling instructions, National Drug Code (if available), “Not for resale” statement, “Office Use Only” statement (if applicable), and a list of active and inactive ingredients; and
- must have a container “from which individual units of the drug are removed for dispensing or administration” that includes a list of active and inactive ingredients, FDA adverse event reporting information, and directions for use.

A registered outsourcing facility must

- register with the Secretary of Health and Human Services (the Secretary) annually (electronically, unless waived by the Secretary) and indicate whether it intends to compound a drug on the Secretary’s list of drug shortages;
- submit a report to the Secretary twice a year identifying the drugs compounded, including the active ingredient and its source, National Drug Code numbers, and other specified information;
- be subject to inspection (pursuant to Section 704 [21 USC 374], which applies to manufacturing facilities) according to a risk-based schedule based on factors such as the compliance history of the outsourcing facility, inherent risk of the drugs being compounded, among others; and
- submit adverse event reports.

The Secretary must

- make outsourcing facility registration information publicly available; and
- issue regulations regarding the list of drugs presenting demonstrable difficulties for compounding after convening and consulting with an advisory committee (to include specified membership) on compounding; regularly review the lists and update as necessary.

The proposed Section 503B would include definitions of compounding, essentially a copy of an approved drug, approved drug, outsourcing facility, and sterile drug.

Title I would amend the FFDCA sections involving prohibited acts (Sec. 301 [21 USC 331]) and misbranded drugs (Sec. 502 [21 USC 352]) to include specified actions regarding compounded drugs. It also would direct the Secretary to promulgate implementing regulations.

Fees

H.R. 3204 would amend the FFDCA to add sections (744J and 744K) addressing user fees. The bill would require the Secretary to collect an annual establishment fee from each outsourcing facility that chooses to register as well as reinspection fees when applicable. The bill specifies the process the Secretary would follow to establish fee amounts, an inflation adjustment factor, an adjustment factor and exceptions for certain small businesses, the crediting and availability of fees, fee collection and the effect of failure to pay fees (which would include deeming a product misbranded and therefore prohibiting its sale). The bill would also require the Secretary to report annually to Congress describing fees collected, entities paying fees, hiring of new staff, use of fees to support outsourcing facility inspections, and the number of inspections and reinspections performed.

The Secretary could use those fees “solely to pay for the costs of oversight of outsourcing facilities,” and the user fee funds would have to be used “to supplement and not supplant” other available federal funds.⁷

Communication with State Boards of Pharmacy

A section of H.R. 3204 titled “Enhanced Communication” would direct the Secretary to receive information from state boards of pharmacy regarding (1) actions taken regarding compounding pharmacies (warning letters, sanctions or penalties, suspension or revocation of state license or registration, or recall of a compounded drug) or (2) “concerns that a compounding pharmacy may be acting contrary to [FFDCA] section 503A [21 USC 353a].” The Secretary would be required to consult with the National Association of Boards of Pharmacy in implementing the submission requirement and to immediately notify state boards of pharmacy when receiving submissions or when the Secretary determines that a pharmacy is acting contrary to FFDCA Section 503A.

GAO Study

H.R. 3204 would require that the Comptroller General review pharmacy compounding in each state, review state laws and policies, assess available tools with which purchasers could determine the safety and quality of compounded drugs, evaluate the effectiveness of communication about compounding among states and between the states and FDA, and evaluate FDA’s implementation of FFDCA Sections 503A [21 USC 353a] and 503B. The report would be due three years after the bill’s enactment.

Drug Supply Chain Security Act

A drug may change hands many times from the point at which it leaves the manufacturer until it reaches the dispenser who provides the drug to a patient. Each step along the way—involving the manufacturer, wholesale distributors, repackagers, third-party logistics providers, and dispensers—presents an opportunity for “contamination, diversion, counterfeiting, and other adulteration.”⁸ Members of Congress, FDA, and industry groups within the supply chain, among others, have looked for a mutually agreeable system to trace and verify the identity of a drug as it travels through the chain.⁹ One goal was the development of a national policy that would be more feasible and effective than a patchwork of varying state requirements. Title II, the proposed Drug Supply Chain Security Act, would, among other things, require

- the creation and continuation of *transaction information*, *transaction history*, and *transaction statements* (beginning no later than January 2, 2015 for manufacturers, wholesale distributors, and repackagers; beginning July 1, 2015 for dispensers);

⁷ Congressional statements that user fee revenue to FDA is to supplement and not supplant or replace appropriated funds have appeared in fee-authorizing legislation since the Prescription Drug User Fee Act in 1992; see CRS Report R42366, *Prescription Drug User Fee Act (PDUFA): 2012 Reauthorization as PDUFA V*, by Susan Thaul.

⁸ Statement of Janet Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration, Department of Health and Human Services, before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, hearing on “Securing Our Nation’s Prescription Drug Supply Chain,” April 25, 2013, <http://www.fda.gov/NewsEvents/Testimony/ucm349186.htm>.

⁹ CRS Report R43106, *Pharmaceutical Supply Chain Security*, by Susan Thaul.

- a product identifier on each package and homogeneous case of a product, to include a standardized numerical identifier (SNI), lot number, and product expiration date (beginning no later than four years after enactment of this bill);
- required verification of the product identifier at the package level (with staggered starting dates: manufacturers four years after enactment of this bill, repackagers five years after enactment, wholesale distributors six years after enactment, and dispensers seven years after enactment);
- registration of wholesale distributors and third-party logistics providers in the states from which they distribute or by the Secretary if the state does not offer such licensure; that the Secretary develop standards for that registration;
- specific activities, following a specified timeline, to implement an interoperable unit-level traceability system ten years after enactment; and
- the development and maintenance of a uniform national policy for the tracing of drug products through the supply chain.

To do so, Title II would amend the FFDCA by adding a subchapter titled Pharmaceutical Distribution Supply Chain that would contain proposed Sections 581 through 585, and by amending Sections 301 [21 USC 331] (prohibited acts), 303 [21 USC 333] (penalties), 502 [21 USC 352] (misbranding), and 503 [21 USC 353] (transaction statements upon wholesale distribution).

Supply Chain Entity Requirements

Proposed FFDCA Section 582 would set out what would be requirements for specific types of entities/activities in the supply chain: manufacturers, wholesale distributors, dispensers, repackagers, and drop shipments. (Proposed Section 581 would provide definitions of the terms used.¹⁰) The next several paragraphs give an overview of those requirements.

(24) TRANSACTION-

(A) IN GENERAL- The term 'transaction' means the transfer of product between persons in which a change of ownership occurs.

(B) EXEMPTIONS- The term 'transaction' does not include—...

[Note: Proposed new Sec. 581 lists 28 exemptions; see H.R. 3204 for details.]

(25) TRANSACTION HISTORY- The term 'transaction history' means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

(26) TRANSACTION INFORMATION- The term 'transaction information' means—

(A) the proprietary or established name or names of the product; (B) the strength and dosage form of the product; (C) the National Drug Code number of the product; (D) the container size; (E) the number of containers; (F) the lot number of the product; (G) the date of the transaction; (H) the date of the shipment, if more than 24 hours after the date of the transaction; (I) the business name and address of the person from whom ownership is being transferred; and (J) the business name and address of the person to whom ownership is being transferred.

¹⁰ Proposed FFDCA Section 581 would define the following terms: affiliate, authorized, dispenser, disposition, distribute or distribution, exclusive distributor, homogeneous case, illegitimate product, licensed, manufacturer, package, individual saleable unit, prescription drug, product, product identifier, quarantine, repackager, return, returns processor or reverse logistics provider, specific patient need, standardized numerical identifier, suspect product, third-party logistics provider, trading partner, transaction, transaction history, transaction information, transaction statement, verification or verify, and wholesale distributor. Proposed definitions of selected terms appear in text boxes in this report.

(27) TRANSACTION STATEMENT- The 'transaction statement' is a statement, in paper or electronic form, that the entity transferring ownership in a transaction—
(A) is authorized as required under the Drug Supply Chain Security Act; (B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act; (C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582; (D) did not knowingly ship a suspect or illegitimate product; (E) had systems and processes in place to comply with verification requirements under section 582; (F) did not knowingly provide false transaction information; and (G) did not knowingly alter the transaction history.

—definitions from H.R. 3204, Sec. 202

The Secretary would have to

- in consultation with federal officials and specified stakeholders and not later than one year after enactment, issue draft guidance to establish “standards for the interoperable exchange” of transaction information, transaction history, and transaction statements;
- establish processes by which supply chain entities could request waivers or exemptions to any requirements in the proposed Section 582 and by which the Secretary could determine specified exceptions; and
- finalize guidance not later than two years after enactment to specify whether and how to exempt products in the supply chain (before the effective date) from product identifier requirements.

Other general provisions would

- provide several exemptions or alternative start dates for requirements relating to providing certain transaction information, transaction history, or transaction statements, or wholesale distributor and third-party logistics provider licensing, for products that were in the supply chain before January 1, 2015 or over the period until the effective dates of required regulations;
- allow an entity that changed a package label solely to add the product identifier (as would be required by this Act) to submit that change to the Secretary in its annual report;
- require, unless the Secretary allows otherwise through guidance, that product identifiers include applicable data in “a 2-dimensional data matrix barcode when affixed to, or imprinted upon, a package” and in “a linear or 2-dimensional data matrix barcode when affixed to, or imprinted upon, a homogeneous case”; and
- allow that verification of the product identifier occur using human- or machine-readable methods.

The first five subsections of the proposed FFDCA Section 582 would set requirements for manufacturers, wholesale distributors, and repackagers. These requirements would generally concern

- product tracing, including responsibility when accepting or transferring a drug, transaction information for returns, and requests for information regarding suspect products;
- product identifiers, beginning with the requirement that manufacturers and repackagers affix a standardized graphic to each package and homogenous case; and

- verification of suspect product, including quarantine, validating the transaction history and transaction information, verifying product identifier, notification of trading partners and the Secretary, maintenance of an electronic database.

(14) **PRODUCT IDENTIFIER**- The term 'product identifier' means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.

(20) **STANDARDIZED NUMERICAL IDENTIFIER**- The term 'standardized numerical identifier' means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

—definitions from H.R. 3204, Sec. 202

Although the approach (regarding, for example, tracing, identifiers, and verification) is consistent across the various entities in the supply chain, the timing and some elements of those requirements vary.

Drug Distribution Security

A second set of subsections in a proposed FFDCA Section 582 describes enhanced drug distribution security provisions, including the development and implementation of an interoperable system of electronic package-level tracing, establishment of national standards for wholesale distributors and third-party logistics providers, a uniform national policy rather than state-specific requirements for drug tracing, and requirements that the Secretary develop guidance documents, hold public meetings, and establish pilot projects.

Interoperable, Electronic Package-Level Tracing

The bill would require that interoperable, electronic tracing of products at the package level go into effect 10 years after enactment (proposed FFDCA Sec. 582(g)). The process would involve transaction information and transaction statements being “exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance” document (described below). Transaction information would include the package-level product identifiers. The bill would require systems and processes, including the standardized numerical identifier, to verify package-level products (according to the proposed required guidance); to respond to requests by the Secretary for transaction information and transaction statements; to gather necessary information; to protect confidential commercial information and trade secrets; and to associate transaction information and transaction statements with a product to allow a saleable return.

The proposed section would allow a dispenser to “enter a written agreement with a third party” to maintain required information and statements. The Secretary would be allowed to “provide alternative methods of requirements,” such as compliance timelines or waivers, for small businesses or in the case of a dispenser’s undue economic hardship.

This section would require that the Secretary enter into a contract for a “technology and software assessment that looks at the feasibility of dispensers with 25 or fewer full-time employees conducting interoperable, electronic tracing of products at the package level.” The contract, which would include consultation with small dispensers, would be required to begin no later than 18 months after final guidance (see below), with the assessment to be completed no later than 8½

years after enactment. The bill specifies the content of the assessment and requirements for public comment both on the statement of work and on the final assessment as well as a public meeting.

The section would direct the Secretary to follow specific procedures when promulgating regulations. These would provide “appropriate flexibility” relating to small businesses and undue economic hardship on dispensers; consider results of pilot projects, public meetings, public health benefits and costs of additional regulations, the required assessment (see above) of small business dispensers. This requirement would not, however, delay the effective date of interoperable unit-level tracking.

Guidance Documents

The Secretary would be required to issue several guidance documents through procedures outlined in the bill. The topics of the guidance documents, along with the timetable the Secretary would be required to meet, are:

- Identification of a *suspect and illegitimate product*; due not later than 180 days after enactment;
- Recommendations for *unit level tracing*; due not later than 18 months after a required public meeting; and
- Updated guidance on *standards for interoperable data exchange*; to be finalized not later than 18 months after required public meeting.

Public Meetings and Pilot Projects

The Secretary would be required to hold at least five public meetings “to enhance the safety and security of the pharmaceutical distribution supply chain.” The first meeting would not be able to be held until one year after enactment; the bill specifies the topics to be addressed in the meetings.

The Secretary would be required to establish at least one pilot project, in coordination with manufacturers, repackagers, wholesale distributors, and dispensers “to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain.” The bill directs the design of such pilots.

The bill directs that neither the public meeting nor the pilot project requirements delay the effective date of interoperable unit-level tracking.

Sunset

Beginning 10 years after enactment—at which time the national, interoperable, unit-level tracing system would go into effect, as would be required by this act—several requirements of the act would have “no force or effect.” These include the exchange of transaction histories among supply chain entities that would be required by proposed FFDCA Section 582.

National Standards for Prescription Drug Wholesale Distributors

The bill would amend FFDCA Section 503(e) [21 USC 353], which currently requires, among other things, that a wholesale distributor (who is not the manufacturer or an authorized distributor of record) be licensed by the state from which it distributes the drug, and that each manufacturer maintain a current list of authorized distributors of record for each drug.

(29) **WHOLESALE DISTRIBUTOR**- The term 'wholesale distributor' means a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 503(e)(4), as amended by the Drug Supply Chain Security Act).

—definition from H.R. 3204, Sec. 202

A proposed amendment to Section 503(e) would add that if that state does not require licensure, the Secretary may provide the licensure (and may collect a fee to reimburse the costs of the licensure program and related periodic inspections). The wholesale distributor would also have to be licensed by the receiving state if that state requires licensure. The licenses would be required to meet the conditions that would be established by a separate section of the act.

Other proposed requirements include that the owner or operator of a wholesale distributor be required to report to the Secretary annually on each license held and contact information of all its facilities. The wholesale distributor must also report on significant federal or state disciplinary actions.

The Secretary would be required to establish by January 1, 2015, and regularly update, a publicly available database of authorized wholesale distributors. The Secretary would provide for state officials to have prompt and secure access to the licensing information. This act would not authorize the Secretary to disclose protected trade secrets or confidential information.

The bill would amend the definition of wholesale distribution to include additional exclusions; would specify that a third-party logistics provider (as would be defined in the act) would not have to be licensed as a wholesale distributor if the third-party logistics provider never assumed ownership of the product; and would define a business entity affiliate.

H.R. 3204 would add a proposed FFDCA Section 583, National Standards for Prescription Drug Wholesale Distributors, which would include standards for storage and handling, records, bonds or other means of security, mandatory background checks and fingerprinting, qualifications for key personnel, prohibited persons, and mandatory physical facility inspection. If the Secretary promulgates regulations pursuant to this section, the Secretary must issue a notice of proposed rulemaking, allow for a comment period, and have the final regulation take effect two years after its publication.

National Standards for Third-Party Logistics Providers

This act would add a proposed FFDCA Section 584, National Standards for Third-Party Logistics Providers, which would require that a third-party logistics provider be licensed by the state from which it distributes the drug, or if that state does not require licensure, by the Secretary (who may collect a fee to reimburse the Secretary for the costs of the licensure program and related periodic inspections). The third-party logistics provider would also have to be licensed by the receiving state if that state requires licensure and the third-party logistics provider is not licensed by the Secretary.

(22) **THIRD-PARTY LOGISTICS PROVIDER**- The term 'third-party logistics provider' means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

—definition from H.R. 3204, Sec. 202

The bill would require annual reports by each facility of a third-party logistics provider to include its licensure and contact information.

The Secretary would be required to issue regulations, not later than two years after enactment, regarding standards for the licensing of third-party logistics providers, to cover third-party accreditation, storage practices (including space, security, written policies and procedures), periodic inspection, prohibited personnel, mandatory background checks, provision of lists (upon request by licensing authority) of all manufacturers, wholesale distributors, and dispensers for which the third-party logistics providers provides services, and license renewal. For regulations promulgated regarding third-party logistics provider licensing, the Secretary would be required to provide a notice of proposed rulemaking, allow for a comment period, and set an effective date one year after the final regulation is issued.

Uniform National Policy

H.R. 3204 would establish a proposed FFDCA Section 585 that would address the relationship of the proposed supply chain requirements to state authorities. Specifically, it would prohibit, from the date of enactment, a state or political subdivision of a state to establish or continue

“any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable under section 503(e) (as amended by such Act) or this subchapter (or regulations issued thereunder), or which are inconsistent with—(1) any waiver, exception, or exemption pursuant to section 581 or 582; or (2) any restrictions specified in section 582.”

Similarly, this section would prohibit, from the date of enactment, a state or political subdivision of state to establish or continue

“any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under section 503(e) (as amended by such Act), in the case of a wholesale distributor, or section 584, in the case of a third-party logistics provider.”

It would also prohibit a state from regulating third-party logistics providers as wholesale distributors. It would allow a state to collect fees for carrying out wholesale distributor and third-party logistics provider licensure. The proposed section would allow states to take specified enforcement, license suspension and revocation, and regulation of licensed entities “in a manner that is consistent with product tracing requirements” under the proposed FFDCA Section 582.

The proposed section would also note an exception:

“Nothing in this section shall be construed to preempt State requirements related to the distribution of prescription drugs if such requirements are not related to product tracing as described in subsection (a) or wholesale distributor and third-party logistics provider licensure as described in subsection (b) applicable under section 503(e) (as amended by the Drug Supply Chain Security Act) or this subchapter (or regulations issued thereunder).”

Penalties

The bill would amend FFDCA Section 301(t) [21 USC 331] making it a prohibited act to fail to comply with requirements in proposed FFDCA Sections 582 and 584 (referring to transaction requirements of entities in the supply chain and national standards for third-party logistics

providers). It would also amend FFDCA Section 502 [21 USC 352] to deem a drug as misbranded if it fails to have the product identifier that would be required by proposed FFDCA Section 582.

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